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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,479	01/21/2004	Naheed Visram	12361-18US JEL	9803
20988	7590	02/14/2006	EXAMINER	
OGILVY RENAULT LLP 1981 MCGILL COLLEGE AVENUE SUITE 1600 MONTREAL, QC H3A2Y3 CANADA			VRETTAKOS, PETER J	
			ART UNIT	PAPER NUMBER
			3739	
DATE MAILED: 02/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/760,479

Applicant(s)

VISRAM ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 29-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-28 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7-6-04, 4-27-04
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The application is published application number 2004/0133113. The publication is classified in US 606/34,41,45.

The Applicant is requested to provide (or check for accuracy) at the beginning of the Specification updated status information (serial numbers and patent numbers) of all related applications. The effective filing date of this application is 1-21-04.

Pending claims as of 1-21-04 are 1-39.

Elected (without traverse) claims 16-28 and 36-39 are examined below.

Non-elected / withdrawn claims are 1-15 and 29-35.

Information Disclosure Statement

The information disclosure statement (IDS) was submitted on 7-6-04 / 4-27-04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 29-35, drawn to an electrosurgical device, classified in class 606, subclass 41.

- II. Claims 16-28 and 36-39, drawn to a method of cutting tissue guiding By ECG, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are **related as process and apparatus for its practice**. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process/method can be performed by mapping electrodes, instead of ECG.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their **different classification**, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Jung-Kay Chiu on 1-17-06 a provisional election was made without traverse to prosecute the invention of Group II, claims 16-28 and 36-39. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 1-15 and 29-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The claims are most consistent with the embodiments depicted in figures 8 and 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-28 and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicant's use of ECG is confusing. By definition, ECGs provide a picture of the heart's electrical activity *sensed from the surface of the skin*. However, the

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specification describes an ECG monitoring mechanism *with an internal electrode*.

Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-28 and 36-39 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Krishnan (US 2004/0133113).

Krishnan discloses a method of surgery comprising the steps of:

- (i) introducing a surgical device (30) into a heart of a patient, the surgical device comprising an elongate member having a distal region and a proximal region, an energy delivery device (electrode, proximate to the distal region capable of cutting material (patented title includes “transseptal puncture”) and an ECG monitoring mechanism (electrograms) for determining ECG in the heart proximate to the distal region;
- (ii) positioning the energy delivery device to a first desired location in the heart adjacent material to be cut;

(iii) delivering energy using the energy delivery device to cut said material (to cause transseptal puncture); and

(iv) monitoring ECG in the heart using the ECG monitoring mechanism in order to determine the position of the surgical device at least one of before and after step (iii).

See paragraphs 21-32.

Note: the Office equates the Applicant's ECG monitoring mechanism to Krishnan's electrogram because the Applicant in paragraph 12 of the specification discloses an ECG related electrode at the distal region of the energy delivery device within the heart. (Electrograms sense the electrical activity of the heart from within the heart, whereas an "ECG" *normally* provides the heart's electrical activity as sensed from the surface of the skin.) This ambiguity in the Application is also addressed above in the 35 USC § 112 rejection.

17. The method as claimed in claim 16 further comprising a step of: (v) advancing the device to a second location. Krishnan discloses dragging the device (paragraphs 57 and 61), anticipating "second location"s.

18. The method as claimed in claim 17 further comprising a step of: (vi) monitoring ECG using the ECG monitoring mechanism at the second location (paragraphs 57 and 61).

19. The method as claimed in claim 16 wherein step (i) comprises introducing the

device into the patient's vasculature. See paragraphs 6 and 79.

20. The method as claimed in claim 19 wherein the step of introducing the device into the patient's vasculature comprises inserting the device into a dilator and a guiding sheath positioned in the patient's vasculature. Also see paragraphs 6 and 79.

21. The method as claimed in claim 20 comprising a step of: (v) advancing the dilator and the sheath to a second location together over the surgical device. See paragraphs 6 and 79.

22. The method as claimed in claim 20 comprising a step of: (v) advancing the dilator, sheath and surgical device all together into a second location (paragraphs 6, 57, 61, 79).

23. The method as claimed in claim 16 wherein the material is tissue located on an atrial septum of the heart. See the first sentence of the Abstract.

24. The method as claimed in claim 18 wherein the ECG monitored at the second location is the ECG in the left atrium (paragraphs 57 - dragging, 61- dragging, 82 – left atrium).

25. The method as claimed in claim 16 wherein step (ii) comprises dragging the surgical

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device about a surface of the heart while simultaneously monitoring ECG to determine the first desired location. See paragraph 57.

26. The method as claimed in claim 25 wherein the first desired location is determined in response to the observation of a distinctive change in the ECG signal. See paragraph 57.

27. The method as claimed in claim 26 wherein the ECG signal at the first desired location is damped (reduced as disclosed in paragraph 57, last sentence) in comparison with the ECG signal monitored otherwise on the surface of the heart as the surgical device is located about the first desired location.

28. The method as claimed in claim 26 wherein the first desired location is a fossa ovalis of the heart. See second sentence of Abstract.

36. A method of cutting tissue at a desired location in a body of a patient comprising the steps of: inserting a surgical device into the body, said surgical device comprising means for cutting material and means for determining a position of the device responsive to ECG within the heart; and positioning said surgical device at the desired location in response to the means for determining a position of the device. (This is addressed above.)

37. The method as claimed in claim 36 comprising the step of: cutting material at the desired location (transseptal puncture, addressed above).

38. The method as claimed in claim 37 comprising the step of: moving said device in the body in response to said means for determining a position of the device (paragraph 57, *inter alia*).

39. The method as claimed in claim 38 comprising re-positioning said device for re-cutting in response to said means for determining a position of the device (paragraphs 57 and 61).

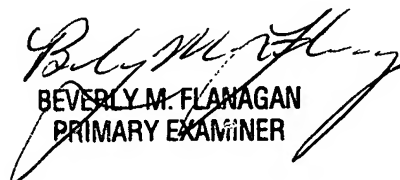

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
February 6, 2006



BEVERLY M. FLANAGAN
PRIMARY EXAMINER